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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/209, 125	12/10/98	AIYAR	J PHM. 70293-US

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EXAMINER

BASI, N

ART UNIT	PAPER NUMBER
1646	9

DATE MAILED: 06/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/209,125</b>	Applicant(s) <b>AIYAR et al</b>
	Examiner <b>Nirmal. S. Basi</b>	Group Art Unit <b>1646</b>

Responsive to communication(s) filed on Apr 6, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-30 is/are pending in the application.

Of the above, claim(s) 6, 7, and 10-30 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-5, 8, and 9 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-30 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on Dec 10, 1998 is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

### **DETAILED ACTION**

1. Response to Restriction requirement filed 4/6/00 has been entered.
2. Amendment filed 12/10/98, paper number 3, is objected to because it introduces a sequence listing without disclosing that the computer readable form in this application is identical with the filed sequence listing and said sequence introduces no new matter. Applicant must provide a statement that the content of the paper and computer readable copies are the same and include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

#### ***Election/Restriction***

3. Applicant's election of Group I, Claims 1-5 and 8-9 in Paper No. 8 (4/6/00), is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 6-7 and 10-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Specification***

- 15 4. The disclosure is objected to because of the following informalities:  
The drawings objected to because each Figure must described separately in the Brief Description of the Drawings. Figure 1 is contained on two separate sheets. Figure 1 must be labeled as Figure 1A and Figure 1B and described in the Brief Description of the Drawings as Figures 1A-1B or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1). Similarly, Figures 2 ,4 and 7 must also be corrected. Figure 9 is objected to because panels A, B and C are not labeled. Figure 10 is

Art Unit: 1646

objected to because panels A and B are not labeled. Figure 11 is objected to because panels A and B are not labeled

Appropriate correction is required.

5                   *Claim Rejection, 35 U.S.C. 112, second paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10       5       Claims 1-5, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15                   Claims 1, 2, 8 and 9 (and dependent claims 3, 4 and 5) are vague and indefinite because claims 1, 2, 8 and 9 recite the term “substantially as depicted”, and it is not clear how far sequences can differ from those of SEQ ID NOS: 2 and 3 and still be substantially the same so that the metes and bounds of the claims can be determined.

Claims 1, 4 and 8 are indefinite for reciting the term “biologically active” or “biologically-effective”, because it is unclear what biological activity is being affected.

20                   Claim 8 is indefinite because the preamble recites “A method for producing cells”, but the method is not directed to the production of cells but to culturing a host cell in order to express a polypeptide. An acceptable method claim must contain three sections: 1) a preamble, 2) method

Art Unit: 1646

steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved.

***Claim Rejections - 35 USC § 112***

5       The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6.       Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides having the sequence shown in SEQ ID NO:2 or encoding the amino acid sequence shown in SEQ ID NO:3, or their complements, does not reasonably provide enablement for the full scope of antisense molecules. The specification does not enable any 15      person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 4 encompasses antisense molecule comprising a polynucleotide which is complimentary to an mRNA encoding the polypeptide of SEQ ID NO:3 or biologically active fragments thereof.. The instant specification discloses that a polynucleotide encoding the amino 20      acid sequence presented in SEQ ID NO:3 can be employed to produce the naturally occurring protein.

Art Unit: 1646

However, the instant specification does not provide an adequate description of antisense molecules. The recitation of antisense implies an intended use for changing the expression of the disclosed protein. Though Applicant discusses antisense nucleic acids on pages 55-56 of the instant specification, these are general teachings, and no guidance is given as to the regions of the mRNA, encoding the polypeptide of SEQ ID NO:3, which would be good targets for antisense polynucleotides. The antisense art is not predictable nor well developed, and so in the absence of any specific guidance or any working example, the specification is not enabled in a manner commensurate in scope with claims to antisense oligonucleotides to an mRNA encoding a polypeptide of SEQ ID NO:3, but it is enabled for a polynucleotide which is complimentary to an mRNA encoding a polypeptide of SEQ ID NO:3.

In the absence of any example of using any oligonucleotide derived from the disclosed cDNA for any type of therapy or to inhibit expression of the calcium channel protein in cells, the Examiner considers that it would require undue experimentation for the ordinary artisan to use the claimed oligonucleotides for such purpose in view of the teachings in the instant specification as filed. There is no guidance in the specification as to which oligonucleotides may be used for these purposes, and it is noted that the antisense arts have not yet matured to the point where such experimentation is considered to be "routine".

Art Unit: 1646

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

5           A person shall be entitled to a patent unless –  
              (b) the invention was patented or described in a printed publication in this or a foreign country or in  
              public use or on sale in this country, more than one year prior to the date of application for patent in the  
              United States.

7.       Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated  
10      by Yokoyama, M et. al. (cited by Applicant). Claims 1-5 and 8 encompass a purified  
          polynucleotide comprising a nucleic acid sequence having the sequence **substantially as**  
          depicted in SEQ ID NO:3, or encoding the polypeptide having the sequence substantially  
          the same as depicted in SEQ ID NO:3, expression vectors, host cells, method of  
          producing said host cells and antisense molecules.

15      Webster's Ninth dictionary defines the word "substantial" as "being largely but  
          not wholly that which is specified". Yokoyama, M et. al disclose a polynucleotide  
          encoding a polypeptide (see Fig 4) that has 43.6% query match and 96.2% to the  
          sequence of SEQ ID NO:2. This degree of similarity would be considered substantial and  
          so anticipates the claims. Also taught are expression vectors and host cells containing said  
20      polynucleotide (materials and methods) antisense constructs of said polynucleotide  
          (Northern Blot analysis). Further , taught are methods of producing cells which express

Art Unit: 1646

the polynucleotide encoding the polypeptide disclosed in Fig 4. Since the specification does not specifically disclose which fragments of SEQ ID NO:3 or SEQ ID NO:2 are biologically active, the fragments disclosed by Yokoyama, M et. al are considered to be inherently active, absent evidence to the contrary.

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### **Claim Rejections, 35 U.S.C. 103**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Art Unit: 1646

Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama, M et. al. (cited by Applicant) in view of Li et al, WO 96/03415, Feb. 8, 1996 (cited by Applicant). Yokoyama, M et. al. disclose a polynucleotide encoding a polypeptide (potassium channel, (see Fig 4)) that has 43.6% query match and 96.2% to the sequence of SEQ ID NO:2. Also taught are expression vectors and host cells containing said polynucleotide (materials and methods)

5 Yokoyama, M et. al. does not teach the method of producing a polypeptide.

Li et al disclose a polynucleotide (SEQ ID NO:3) encoding a potassium channel polypeptide (SEQ ID NO:4). Also taught are expression vectors and host cells (page 10-10 12), production of encoded polypeptide by recombinant methods (page 13-16).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to use the host cell of Yokoyama, M et. al for the production of gene product encoded by SEQ ID NO:3 using the methods of Li et. al. The ordinary artisan would have been motivated to use the host cell of Yokoyama, M et. al in the method of Li et al for the production of gene product encoded by SEQ ID NO:3 for determination of the activity of the translated protein and the production of antibodies. Li et al discloses that antibodies (page 22) can be generated against the polypeptides encoding the potassium channel.

15 The ordinary artisan would have expected success at using the above mentioned method for producing polypeptide using the host cell of Yokoyama, M et. al (containing a cloned

Art Unit: 1646

potassium) because Li et al has successful cloned, expressed and isolated potassium channel proteins by similar methods.

No claim is allowed.

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**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Thursday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi  
Art Unit 1646  
June 12, 2000

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER